

# TENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 180.0012 0201	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/US2005/007857	International filing date ( <i>day/month/year</i> ) 10 March 2005 (10.03.2005)	Priority date ( <i>day/month/year</i> ) 10 March 2004 (10.03.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant CREIGHTON UNIVERSITY		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 338 82 70	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Date of issuance of this report 13 September 2006 (13.09.2006)</td> </tr> <tr> <td style="padding: 5px;">Authorized officer  Dorothee Mülhausen  e-mail: pt01@wipo.int</td> </tr> </table>	Date of issuance of this report 13 September 2006 (13.09.2006)	Authorized officer  Dorothee Mülhausen  e-mail: pt01@wipo.int
Date of issuance of this report 13 September 2006 (13.09.2006)			
Authorized officer  Dorothee Mülhausen  e-mail: pt01@wipo.int			

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

REC'D 30 NOV 2005

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To:

see form PCT/ISA/220

PCT/

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/US2005/007857

International filing date (day/month/year)  
10.03.2005

Priority date (day/month/year)  
10.03.2004

International Patent Classification (IPC) or both national classification and IPC  
C07K16/28, A61K39/395, G01N33/53, C07K14/72, C12N5/10

Applicant  
CREIGHTON UNIVERSITY

### 1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/007857

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☒ in written format
    - ☒ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/007857

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 41-46

because:

- ☒ the said international application, or the said claims Nos. 41-46 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (*specify*):

**see separate sheet**

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
  - the written form ☐ has not been furnished
  - ☐ does not comply with the standard
  - the computer readable form ☐ has not been furnished
  - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/007857

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	1-52
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-52
Industrial applicability (IA)	Yes: Claims	1-40,47-52
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**Re Item III**

Claims 41-46 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

**Re Item V.**

- 1 Reference is made to the following documents:  
D1 : WO 01/00823 A (EUROPEAN MOLECULAR BIOLOGY LABORATORY;  
GANNON, FRANK; DENGGER, STEFANIE) 4 January 2001 (2001-01-04)  
D2 : DATABASE EMBL-SVA [Online] 28 August 2003 (2003-08-28), "Homo sapiens  
mRNA; cDNA DKFZp686N23123 (from clone DKFZp686N23123)"  
XP002354993 retrieved from EBI accession no.  
EM\_PRO:BX640939 Database accession no. BX640939.1

**2 Independent claim 1**

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 1 does not involve an inventive step in the sense of Article 33(3)PCT.
  - 2.1.1 Document D1, which is considered to represent the most relevant state of the art to the subject matter of claim 1, discloses (the references in parentheses applying to this document): Antibodies to splice variants of Estrogen Receptor alpha (p. 6, 1.5-16, fig.6 claims 7,8), and methods for finding agents binding to these splice variants(claim 9).
  - 2.1.2 The subject-matter of independent claim 1 differs from the disclosure of D1 in that : the variant of SEQ ID NO:1 is not mentioned in D1. No specific technical effect can be attributed to this difference.

- 2.1.3 The problem to be solved by the present invention may therefore be regarded as the need for further splice variants of the Estrogen Receptor alpha.
- 2.1.4 In view of D2 the solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons: D2 discloses peptide and nucleotide sequences which according to the annotation concern a differentially spliced estrogen receptor alpha. The peptide sequence is identical to SEQ ID NO: 20 and its fragment SEQ ID NO: 1.
- 2.1.5 Therefore the features disclosed in D1 and D2 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 1 thus cannot be considered inventive (Article 33(3) PCT).

### **3 Other independent claims**

The same reasoning as under Item 2 applies, mutatis mutandis to the subject-matter of independent claims 12,15,16,17,21,25,29,38,41,47,50,51,52 which therefore also lack inventive step.

### **4 Dependent claims**

Dependent claims 2-11,13,14,18-20,22-24,26-28,30-37,39,42-46,48,49 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, involve an inventive step with respect to the prior art named in the present proceedings. The reasons therefor are that the additional features of the said dependent claims are a combination of features obvious to the skilled person in consideration of D1 or D2 or any of the documents mentioned in the International Search Report, or they concern minor modifications which lie within the normal practice of the skilled person.

**5 Method of treatment**

For the assessment of the present claims 41-46 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.